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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,295	11/03/2003	Nigel Benjamin	14-06	5269

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GREENLEE WINNER AND SULLIVAN P C
4875 PEARL EAST CIRCLE
SUITE 200
BOULDER, CO 80301

EXAMINER	
PAK, JOHN D	
ART UNIT	**PAPER NUMBER**
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/701,295	BENJAMIN ET AL.	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/3/2007 has been entered.

Applicant is advised to correct "alkaline metal" (emphasis added) in claim 29 as --- alkali metal --- .

The claims have been substantially restored to the form originally presented at the beginning of prosecution of this application with two exceptions.

The first exception of note is in characterizing the *released substance after mixing* the acid and nitrite source as "nitrite ions." Applicant does not explain where in the original disclosure this feature finds support. Throughout the original disclosure, the mixture of acid + nitrite source is disclosed to release oxides of nitrogen, e.g. nitric oxide, nitrous oxide, nitrogen dioxide and dinitrogen trioxide (specification page 1, lines 34-37; page 28, lines 28-32). If original claim 1 ("release NO or NO_2 ions") is being relied on for support, applicant is requested to verify the accuracy of this disclosure since the rest of the original disclosure does not correspond to this feature.

The second exception of note is in the phrase "said acidifying agent is present in an amount sufficient to establish a pH at an environment of use below 4" (emphasis

added). The original disclosure provides for reducing the pH to below 4 but not exactly establishing the pH to below 4 (see for example original claims 1, 7, 9, and throughout the original specification). The Examiner finds the scope of "reduce" to be different from that of "establish." "Reduce" means the pH was higher and it was subsequently lowered. "Establish" includes maintaining the pH at below 4, wherein the previous pH could also have been below 4 (thus the pH is not reduced but merely maintained). Therefore, there is a difference in scope, and new matter issue is raised with respect to this second exception.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

For the reasons stated above, "amount sufficient to establish a pH at an environment of use below 4" (emphasis added) lacks adequate descriptive support from the originally filed disclosure. This feature reads on not reducing but maintaining the pH at below 4. The amount of the acid could therefore be less than originally disclosed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 depends on the now-canceled claim 27. Subject matter of claim 32 therefore cannot be determined. No further examination on the merits is possible for claim 32.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28, 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Biosis abstract 1987:466265.

Instant claims 28 and 30 are claimed as "A dosage form." The organic acidifying agent and the nitrite ion source are "separately disposed for admixture to release nitrite ions at the intended environment of use."

Biosis abstract 1987:466265 discloses topical staining with silver nitrate followed by application of 5% or 10% salicylic acid in petrolatum.

While the cited reference does not state in verbatim language a dosage form, the same form is necessarily disclosed. Separate containment of silver nitrate and salicylic acid is explicitly disclosed. Applicant's dosage form does not require any specificity as to how the acid and the nitrate components are physically connected relative to each other within the dosage form. Therefore, it is seen to be sufficient that the cited reference clearly discloses those ingredients to be separately held prior to their final admixture.

The claim feature that the acidifying agent be present "in an amount sufficient to establish a pH at an environment of use below 4" is noted. It is noted that the cited reference here discloses 5% and 10% salicylic acid. Applicant's specification Example 7 on page 21 shows patient trials with 5% salicylic acid in a cream carrier. The prior art 5% and 10% is therefore seen to be within applicant's claim language[1].

The feature of releasing "nitrite ions" is noted. The Examiner's position is that since the same nitrite and the same organic acid are mixed in the prior art, the same substance as claimed by applicant must necessarily be released.

As for the pharmaceutical carriers, the petrolatum for salicylic acid is sufficient. With respect to silver nitrate, it is noted that silver nitrate is disclosed as a stain to be applied first. Since silver nitrate is a solid, the stain would have been immediately

[1] Also, salicylic acid is soluble in water at 1 g/460 ml. So 2.17 g is soluble in 1 liter. The Merck Index (already of record) shows pH of saturated salicylic acid is 2.4. since 2.17 g/l is the point of saturation, this means about 0.2% salicylic acid in water has a pH of 2.4. Therefore, the prior art 5% or 10% salicylic acid would clearly provide a pH that is "below 4" at an intended environment of use.

envisaged as a solution form. With the solution being topically applied, it meets the pharmaceutically acceptable carrier feature.

For these reasons, Biosis abstract 1987:466265 anticipates applicant's claims 28 and 30.

Claims 28-29 and 31 rejected under 35 U.S.C. 102(b) as being anticipated by Mardi et al. (US 4,595,591).

Mardi et al. explicitly disclose a composition in the form of "two vials, the first containing a sodium nitrite solution, the second a solution of other components" (column 9, lines 58-61). The "other components" in the second vial contains nitric acid in a concentration and amount that gives the combined solutions a pH of below about 1 and **organic acids** (column 2, lines 26-37; column 5, lines 10-62). Mardi's composition is used to treat conditions such as verruca vulgaris and condyloma acuminatum (column 12, line 60; claim 1). Nitrites are released from the reaction of the nitric acid and organic acid (column 5, lines 10-25).

The claims are thereby anticipated. The intended use claim feature is met because verruca vulgaris and condyloma acuminatum are conditions that are caused by the human papillomavirus. Mardi's treatment is therefore an antiviral treatment.

For these reasons, the claims are deemed to be anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mardi et al.

Mardi's teachings are set forth above and the discussion there is incorporated herein by reference. Mardi et al. disclose also the use keratolytic organic acids such as salicylic acid (column 5, lines 49-53).

The dosage form of claims 28-29 and 31 would have been obvious since the same dosage form is explicitly taught by Mardi et al. Use of salicylic acid (claim 30) is taught by Mardi et al. Hence, the ordinary skilled artisan would have been motivated to arrive at a dosage form as claimed. The ordinary skilled artisan would have found it obvious to follow Mardi's teachings by providing separate vials of ingredients, wherein the vial that contains the "other components" in the second vial contains nitric acid in a concentration and amount that gives the combined solutions a pH of below about 1 and organic acids, including salicylic acid for keratolytic benefits. At such a low pH, establishing a pH of below 4 at the intended environment of use would have been obvious.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited reference.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

John Pak
Primary Examiner
Technology Center 1600